

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: John B. Harley and Judith A. James

Serial No.: Divisional of 10/012,756

Art Unit: Not Yet Assigned

Filed: June 27, 2003

Examiner: Not Yet Assigned

For: *DIAGNOSTICS AND THERAPY OF EPSTEIN-BARR VIRUS IN AUTOIMMUNE DISORDERS*

Commissioner for Patents
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INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicants submit an Information Disclosure Statement, including twenty-three (23) pages of Form PTO-1449. All of the documents cited below were cited by or submitted to the Patent Office in Application Serial No. 10/012,756, filed October 24, 2001, to which the present application claims priority. Pursuant to 37 C.F.R. §1.98(d), Applicants are not enclosing copies of these publications. Copies will be provided upon request, however.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) prior to a first Office Action on the merits. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 50-1868.

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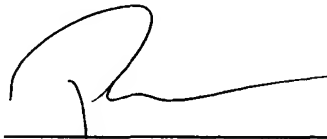
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Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,



Patrea/L. Pabst
Reg. No. 31,284

Dated: June 27, 2003

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		Filing Date	June 27, 2003
		First Named Inventor	John B. Harley
		Group Art Unit	
		Examiner Name	
Sheet 1 of 23	Attorney Docket Number	OMRF 161 DIV (2)	

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		EP	0 113 431		Yeshiva University	07-18-1984		
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		PCT	WO 86/01210		Scripps Clinic Res.	02-27-1986		
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		PCT	WO 91/11718		Board of Regents of the University of Oklahoma	08-08-1991		
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		PCT	WO 91/18920		Neosystem	12-12-1991		
		PCT	WO 93/21223		Board of Regents of the University of Oklahoma	10-28-1993		
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		PCT	WO 94/02509		Rijksuniversiteit Leiden	02-03-1994		
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		BLANK, et al., "Sex Hormone Involvement in the Induction of Experimental Systemic Lupus Erythematosus by a Pathogenic anti-DNA Idiotype in Naive Mice," <i>J. Rheumatol.</i> 17:311-317 (1990).	
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Substitute for form 1449A/PTO		Completeness	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	Divisional of 10/012,756
		Filing Date	June 27, 2003
		First Named Inventor	John B. Harley
		Group Art Unit	
		Examiner Name	
Sheet 6 of 23	Attorney Docket Number	OMRF 161 DIV (2)	

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
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		CRONE, et al., "Viral Transcription is Necessary and Sufficient for Vesicular Stomatitis Virus to Inhibit Maturation of Small Nuclear Ribonucleoproteins," <i>Journal of Virology</i> 63(10):4172-4180 (1989).	
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		Filing Date	June 27, 2003
		First Named Inventor	John B. Harley
		Group Art Unit	
		Examiner Name	
Sheet 7 of 23	Attorney Docket Number	OMRF 161 DIV (2)	

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
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		ESQUIVEL, et al., "Induction of Autoimmunity in Good and Poor Responder Mice with Mouse Thyroglobulin and Lipopolysaccharide," <i>J. Exp. Med.</i> 145:1250-1263 (1977).	
		EVANS & NIEDERMAN, "Epstein-Barr virus" in <i>Viral Infections in Humans</i> , 3rd ed. Evans, A.S. ed. pp 265-292 (Plenum, New York City 1989).	
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		FOX, "Sjogren's Syndrome," <i>Current Opin. Rheum.</i> 7:409-416 (1995).	
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		Filing Date	June 27, 2003
		First Named Inventor	John B. Harley
		Group Art Unit	
		Examiner Name	
Sheet 8 of 23	Attorney Docket Number	OMRF 161 DIV (2)	

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		FOX, et al., "Potential Role of Epstein-Barr Virus in Sjogren's Syndrome and Rheumatoid Arthritis," <i>J. Rheumatol.</i> 19:18-24 (1992).	
		FRICKE, et al., "Induction of Experimental Systemic Lupus Erythematosus in Mice by Immunization with a Monoclonal Anti-La Autoantibody," <i>Intern. Immunol.</i> 2:225-230 (1990).	
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		Application Number	
		Divisional of 10/012,756	
		Filing Date	
		June 27, 2003	
		First Named Inventor	
John B. Harley			
Group Art Unit			
Examiner Name			
Sheet	9	of	23
Attorney Docket Number		OMRF 161 DIV (2)	

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
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		GRABOWSKI, et al., "Drosophila AP3, a Presumptive DNA Repair Protein, is Homologous to Human Ribosomal Associated Protein PO," <i>Nucleic Acids Research</i> 19(15):4297 (1991).	
		GU, et al., "First EBV Vaccine Trial in Humans Using Recombinant Vaccinia Virus Expressing the Major Membrane Antigen," <i>Dev. Biol. Stand.</i> 84:171-177 (1995).	
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		HARLEY & GAITHER, "Autoantibodies" <i>Rheum. Dis. Clin. N. Amer.</i> 14:43-56 (1992).	
		HARLEY & JAMES, "Review Articles: Autoepitopes in Lupus," <i>J. Lab. Clin. Med.</i> 126(6):509-516 (1995).	
		HARLEY, et al., "Gene Interaction at HLA-DQ Enhances Autoantibody Production in Primary Sjogren's Syndrome," <i>Science</i> 232:1145-1147 (1986).	

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		Application Number	Divisional of 10/012,756
		Filing Date	June 27, 2003
		First Named Inventor	John B. Harley
		Group Art Unit	
		Examiner Name	
Sheet 10 of 23	Attorney Docket Number	OMRF 161 DIV (2)	

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		HARLEY, et al., "Anti-Ro (SS-A) and Anti-La (SS-B) in Patients with Sjogren's Syndrome," <i>Arthritis Rheum.</i> 29:196-206 (1986).	
		HARLEY, et al., "Epstein-Barr virus infection may be an environmental risk factor for systemic lupus erythematosus in children and teenagers," <i>Arthritis Rheum.</i> 42(8):1782-3 (1999).	
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		HINTERBERGER, "Isolation of Small Nuclear Ribonucleoproteins Containing U1, U2, U4, U5, and U6 RNAs," <i>J. Biol. Chem.</i> 258:2604-2613 (1983).	
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		HUANG, et al., "Human Anti-Ro Autoantibodies Bind Peptides Accessible to the Surface of the Native Ro Autoantigen," <i>Scand. J. Immunol.</i> 41:220-228 (1995).	
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		HURD, et al., "Formation of Leukocyte Inclusions in Normal Polymorphonuclear Cells Incubated with Synovial Fluid," <i>Arthritis Rheum.</i> 13:724-733 (1970).	

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		Application Number	Divisional of 10/012,756		
		Filing Date	June 27, 2003		
		First Named Inventor	John B. Harley		
		Group Art Unit			
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		INOUE, et al., "Analysis of Antibody Titers to Epstein-Barr Virus Nuclear Antigens in Sera of Patients with Sjogren's Syndrome and with Rheumatoid Arthritis," <i>J. Infect. Dis.</i> 164:22-28 (1991).	
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		JAMES & HARLEY, "A model of peptide-induced lupus autoimmune B cell epitope spreading is strain specific and is not H-2 restricted in mice," <i>J. Immunol.</i> 160(1):502-8 (1998).	
		JAMES & HARLEY, "Linear Epitope Mapping of an Sm B/B' Polypeptide," <i>J. Immunol.</i> 148:2074-2079 (1992).	
		JAMES & HARLEY, "Peptide Autoantigenicity of the Small Nuclear Ribonucleoprotein C," <i>Clin. And Exp. Rheum.</i> 13:299-305 (1995).	
		JAMES & HARLEY, "Sequential Fine Specificity of the Small Nuclear Ribonuclear Protein C," <i>Clinical Res.</i> 41(2):PA393 (1993).	
		JAMES, et al., "Immunoglobulin Epitope Spreading and Autoimmune Disease After Peptide Immunization: Sm B/B'-derived PPPGMRPP and PPPGIRGP Induce Spliceosome Autoimmunity," <i>J. Exp. Med.</i> 181:453-461 (1995).	
		JAMES, et al., "An increased prevalence of Epstein-Barr virus infection in young patients suggests a possible etiology for systemic lupus erythematosus," <i>J. Clin. Invest.</i> 100:3019-26 (1997).	
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		JAMES, et al., "Inbred Mice Strains Differ in Their Capacity to Develop Spliceosomal Autoimmunity After Peptide Immunization," <i>Arthritis Rheum.</i> 38:S226 (1995).	
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		KAUFMAN, et al., "In Vivo Binding of Gram-Negative Bacterial Peptides to Hla-B27: A Possible Relationship to Anklosing spondylitis Pathogenesis," <i>Arthritis Rheum.</i> 39:S298 (1996)	
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	Divisional f 10/012,756
		Filing Date	June 27, 2003
		First Named Inventor	John B. Harley
		Group Art Unit	
		Examiner Name	
Sheet 13 of 23	Attorney Docket Number	OMRF 161 DIV (2)	

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		KURILLA, et al., "The Leader RNA of Vesicular Stomatitis Virus is Bound by a Cellular Protein Reactive with Anti-La Lupus Antibodies," <i>Cell</i> 34:837-845 (1983).	
		KUZUSHIMA, et al., "Establishment of Anti-Epstein-Barr Virus (EBV) Cellular Immunity by Adoptive Transfer of Virus-Specific Cytotoxic T Lymphocytes from an HLA-matched Sibling to a Patient with Severe chronic Active EBV Infection," <i>Clin. Exp. Immunol.</i> 103:192-198 (1996).	
		LARSEN, et al., "Epstein-Barr Nuclear Antigen and Viral Capsid Antigen Antibody Titers in Multiple Sclerosis," <i>Neurology</i> 35:435-438 (1985).	
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		LEE, et al., "Cardiac Immunoglobulin Deposition in Congenital heart Block Associated with Maternal Anti-Ro Autoantibodies," <i>Am. J. of Med.</i> 83:793-796 (1987).	
		LEE, et al., "The Recognition of Human 60-kDa Ro Ribonucleoprotein Particles by Antibodies Associated with Cutaneous Lupus and Neonatal Lupus," <i>J. Investigative Dermatology</i> 107(1):225-228 (1996).	
		LEFF, "Maverick Herpes Receptor Sparks Search for KS Drug," <i>Bio World Today</i> 8(17):1 (1997).	
		LEHMAN, et al., "Spreading of T-Cell Autoimmunity to Cryptic Determinants of an Autoantigen," <i>Nature</i> 356:155-157 (1992).	
		LERNER & STEITZ, "Antibodies to Small Nuclear PNAs Complexed with Proteins are Produced by Patients with Systemic Lupus Erythematosus," <i>Proc. Natl. Acad. Sci. USA</i> 76:5495-5499 (1979).	
		LERNER, et al., "Are snRNPs Involved in Splicing?" <i>Nature</i> 283:220-224 (1980).	

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		LEVITSKAYA, "Inhibition of Antigen Processing by the Internal Repeat Region of the Epstein-Barr Virus Nuclear Antigen-1," <i>Nature</i> 375:685-688 (1995).	
		MADDISON, et al., "Quantitation of Precipitating Antibodies to Certain Soluble Nuclear Antigens in SLE," <i>Arthritis Rheum.</i> 20:819-824 (1977).	
		MAITLAND, "Frequency of EBV-DNA Detection in Sjogren's Syndrome," <i>Am. J. Med.</i> 96:97 (1994).	
		MANFREDI, et al., "Molecular Anatomy of an Autoantigen: T and B Epitopes on the Nicotinic Acetylcholine Receptor in Myasthenia Gravis," <i>J. Lab. Clin. Med.</i> 120:13-21 (1992).	
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		MATTER, et al., "Molecular Characterization of Ribonucleoprotein Antigens Bound by Antinuclear Antibodies," <i>Arthritis Rheum.</i> 25:1278-1283 (1982).	
		MATTIOLI, et al. "Physical Association of Two Nuclear Antigens and Mutual Occurrence of Their Antibodies: The relationship of the SM and RNA protein (MO) Systems in SLE Sera," <i>J. Immunol.</i> 110:1318-1324 (1973).	
		MCALLISTER, et al., "cDNA Sequence of the rat U snRNP-associated Protein N: Description of a Potential Sm Epitope," <i>EMBO J.</i> 8:1177-1181 (1989).	
		MENDLOVIC, et al., "Induction of an SLE-Like Disease in Mice by a Common Anti-DNA Idiotype," <i>Proc. Natl. Acad. Sci. USA</i> 85:2260-2264 (1988).	
		MENDLOVIC, et al., "The Genetic Regulation of the Induction of Experimental SLE," <i>Immunology</i> 69:228-236 (1990).	

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		MENDLOVIC, et al., "The Role of Anti-Idiotypic Antibodies in the Induction of Experimental Systemic Lupus Erythematosus in Mice," <i>Eur. J. Immunol.</i> 19:729-732 (1989).	
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		MIYASHITA, et al., "A Novel Form of Epstein-Barr Virus Latency in Normal B Cells In Vivo," <i>Cell</i> , 80:593-601 (1995).	
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		MORLAND, et al., "Anti-idiotypic and Immunosuppressant Treatment of Murine Lupus," <i>Clin. Exp. Immunol.</i> 83(1):126-132 (1991).	
		MORSHED, et al., "Increased Expression of Epstein-Barr Virus in Primary Biliary Cirrhosis Patients," <i>Gastroenterol. Jpn.</i> 27(6):751-758 (1992).	
		MOSIER, et al., "Transfer of a functional human immune system to mice with severe combined immunodeficiency," <i>Nature</i> 335:256-259 (1988).	
		MUNVES, et al., "Antibodies to Sm and RNP," <i>Arthritis Rheum.</i> 26:848-853 (1983).	
		NEWELL & STEVENS, "E.B. Virus Antibody in Systemic Lupus Erythematosus," <i>Lancet</i> 1:652 (1971).	

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		NEWKIRK, et al., "Detection of Cytomegalovirus, Epstein-Barr Virus and Herpes Virus-6 in Patients with Rheumatoid Arthritis With or Without Sjogren's Syndrome," <i>Br. J. Rheum.</i> 33:317-322 (1994).	
		NICHOLSON, "A T cell receptor antagonist peptide induces T cells that mediate bystander suppression and prevent autoimmune encephalomyelitis induced with multiple myelin antigens," <i>Proc. Natl. Acad. Sci. USA</i> 94:9279-9284 (1997).	
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		PALFI, et al., "Purification of the Major UsnRNPs from Broad Bean Nuclear Extracts and Characterization of their Protein Constituents," <i>Nucleic Acids Res.</i> 17:1445-1458 (1989).	
		PETERSEN, et al., "Altered Immune Response to Glycine-Rich Sequences of Epstein-Barr Nuclear Antigen-1 in Patients with Rheumatoid Arthritis and Systemic Lupus Erythematosus," <i>Arthritis Rheum.</i> 33:993-1000 (1990).	
		PETTERSSON, et al., "The Structure of Mammalian Small Nuclear Ribonuceoproteins," <i>J. Biol. Chem.</i> 259:5907-5914 (1984).	
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		PFLUGFELDER, et al., "Epstien-Barr Virus and the Lacrimal Gland Pathology of Sjogren's Syndrome," <i>Am. J. Pathol.</i> 143:49-64 (1993).	
		PHILLIPS & CHRISTIAN, "Myxovirus Antibody Increases in Human Connective Tissue Disease," <i>Science</i> 168:982-4 (1970).	
		PHILLIPS, et al., "Viruses and Systemic Lupus Erythematosus," <i>Lancet</i> 1:1449 (1973).	

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		QUALTIERE & PEARSON, "Radioimmune Precipitation Study Comparing the Epstein-Barr Virus Membrane Antigens Expressed on P3HR-1 Virus-Superinfected Raji Cells to those Expressed on Cells in a B-95 Virus-Transformed Produced Culture Activated with Tumor-Promoting Agent (TPA)," <i>Virology</i> 102:360-369 (1980).	
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		RAVIRAJAN & STAINES, "Involvement in Lupus Disease of Idiotypes Id.F-423 and Id.IV-228 Defined, Respectively, Upon Foetal and Adult MRL/Mp-lpr/lpr DNA-binding Monoclonal Autoantibodies" <i>Immunology</i> 74:342-347 (1991).	
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		RHODES, et al., "Human Immune Responses to Synthetic Peptides from the Epstein-Barr Nuclear Antigen," <i>J. Immunol.</i> 134:211-216 (1985).	
		ROKEACH, et al., "Primary Structure of a Human Small Nuclear Ribonucleoprotein Polypeptide as Deduced by cDNA Analysis," <i>J. Biol. Chem.</i> , 264:5024-30 (1989).	

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		SCOFIELD, "A Common Autoepitope Near the carboxyl Terminus of the 60-kD Ro Ribonucleoprotein: Sequence Similarity with a Viral Protein," <i>Journal of Clinical Immunology</i> 11(6):378-388 (1991).	
		SCOFIELD, "Autoimmune Thyroid Disease in Systemic Lupus Erythematosus and Sjogren's Syndrome," <i>Clin. Exp. Rheum.</i> 14:321-330 (1996).	

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		SCOFIELD, "HLA-B27 Binding of Peptide From Its Own Sequence and Similar Peptides From Bacteria: Implications For Spondyloarthropathies," <i>Lancet</i> , 345:1542-1544 (1995).	
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		SHOENFELD, et al., "Pathogenic idiotypes of autoantibodies in autoimmunity: lessons from new experimental models of SLE," <i>FASEB J.</i> 4:2646-2651 (1990).	
		SILLIKENS, et al., "cDNA Cloning of the Human U1 snRNA-Associated A Protein: Extensive Homology Between U1 and U2 snRNP-Specific Proteins," <i>EMBO Journal</i> 6:3841-3848 (1987).	

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		Application Number	Divisional f 10/012,756		
		Filing Date	June 27, 2003		
		First Named Inventor	John B. Harley		
		Group Art Unit			
		Examiner Name			
Sheet	20	of	23	Attorney Docket Number	OMRF 161 DIV (2)

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Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		SILLIKENS, et al., "Human U1 snRNP-specific C Protein: Complete cDNA and Protein Sequence and Identification of a Multigene Family in Mammals," <i>Nucleic Acids Res.</i> 16:8307-21 (1988).	
		SINGH, et al., "Decreased Incidence of Viral Infections in Liver Transplant Recipients - Possible Effects of FK506?," <i>Digestive Dis. Sci.</i> 39:15-18 (1994).	
		SPRITZ, et al., "The Human U1-70K s.n. RNP Protein: cDNA Cloning, Chromosomal Localization, Expression, Alternative Splicing and RNA-binding," <i>Nucleic Acid Res.</i> 15:10373-91 (1987).	
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		The Medical Letter on Drugs and Therapeutics 37(951):55-57 (June 23, 1995).	
		THEISSEN, et al., "Cloning of the Human cDNA for the U1 RNA-associated 70K Protein," <i>EMBO J.</i> 5:3209-17 (1986).	
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		TSAL, et al., "Detection of Epstein-Barr Virus and Cytomegalovirus Genome in White Blood Cells from Patients with Juvenile Rheumatoid Arthritis and Childhood Systemic Lupus Erythematosus," <i>Int. Arch. Allergy Immunol.</i> 106:235-240 (1995).	
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		VAN DAM, et al., "Cloned Human snRNP Proteins B and B' Differ Only in Their Carboxy-Terminal Part," <i>EMBO J.</i> 8(12):3853-3860 (1989).	
		VAN VENROOIJ, et al., "B Cell Epitopes on Nuclear Autoantigens," <i>Arthritis and Rheumatism</i> 37(5):608-616 (1994).	

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		VANDENBARK, et al., "Effects of vaccination with T cell receptor peptides: Epitope switching to a possible disease-protective determinant of myelin basic protein that is cross-reactive with a TCR BV peptide," <i>Immunology and Cell Biology</i> 76:83-90 (1998).	
		VENABLES, et al., "Persistence of Epstein-Barr Virus in Salivary Gland Biopsies from Healthy Individuals and Patients with Sjogren's Syndrome," <i>Clin. Exp. Immunol.</i> , 75:359-364 (1989).	
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		VIRJI & HECKELS, "Location of a Blocking Epitope on Outer-membrane Protein III of Neisseria Gonorrhoeae by Synthetic Peptide Analysis," <i>J. Gen. Microbiol.</i> 135:1895-1899 (1989).	
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		WHITTINGHAM, et al., "Epstein-Barr Virus as an Etiological Agent in Primary Sjogren's Syndrome," <i>Med. Hypothesis</i> , 22:373-386 (1987).	
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		YOKOCHI, et al., "Hight Titer of Antibody to the Epstein-Barr Virus Membrane Antigen in Sera from Patients with Rheumatoid Arthritis and Systemic Lupus Erythematosus," <i>J. Rheumatol.</i> 16:1029-1032 (1989).	
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		ZELLER, et al., "Nucleocytoplasmic Distribution of snRNPs and Stockpiled snRNA-Binding Proteins During Oogenesis and Early Development in <i>Xenopus laevis</i> ," <i>Cell</i> 32:425-434 (1983).	

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